FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

IN RE BARD IVC FILTERS PRODUCT LIABILITY LITIGATION, SHERR-UNA BOOKER, *Plaintiff-Appellee,* v. C. R. BARD, INC., a New Jersey corporation; BARD PERIPHERAL VASCULAR, INC., a subsidiary and/or Division of defendant C.R. Bard, Inc., an Arizona corporation, *Defendants-Appellants.*	No. 18-16349 D.C. Nos. 2:15-md-02641-DGC 2:16-cv-00474-DGC OPINION

Appeal from the United States District Court
for the District of Arizona
David G. Campbell, District Judge, Presiding

Argued and Submitted February 3, 2020
Phoenix, Arizona

Filed August 13, 2020

Before: Susan P. Graber, Andrew D. Hurwitz, and Eric D. Miller, Circuit Judges.

Opinion by Judge Miller

SUMMARY*

Preemption / Medical Devices

The panel affirmed the district court's judgment in favor of a plaintiff who brought product-liability claims based on injuries she sustained from a medical device designed and manufactured by C.R. Bard, Inc.

Plaintiff brought this action in the District of Arizona as part of a multidistrict litigation, asserting claims under Georgia law. Bard filed an omnibus motion for summary judgment for all cases in the multidistrict litigation, arguing that the federal Medical Device Amendments of 1976 preempted all state-law claims.

The case involved Bard's G2 Filter – an "intravascular filter" that the Food and Drug Administration ("FDA") reclassified as a Class II device with three "special controls."

The panel held that, because Bard's preemption defense presented a purely legal question, the panel would consider the merits of the district court's denial of its motion for summary judgment. The panel held that Bard's preemption

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

argument failed because plaintiff's claim rested on an asserted state-law duty to warn of the risks posed by the particular design of Bard's G2 Filter, and the FDA had not imposed any requirements related to the design of that device or how a device of that design should be labeled.

Bard next argued that the district court erred in denying summary judgment on plaintiff's negligent failure-to-warn claim because Georgia law did not recognize a duty to warn of the comparative risks posed by different products. The panel held that Georgia courts had not adopted a categorical prohibition on basing a failure-to-warn claim on the absence of a comparative warning. The panel concluded that the district court correctly allowed a jury to decide the adequacy of the warning here.

Bard argued that the district court erred by denying its renewed motion for judgment as a matter of law, which challenged the evidentiary sufficiency for the punitive damages award. The panel held that Bard's challenge to the punitive damages award was largely derivative of its argument that it had no duty to warn of comparative risks. The panel concluded that the evidence was adequate to support the jury's award of punitive damages.

COUNSEL

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OPINION

MILLER, Circuit Judge:

Sherr-Una Booker sued C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"), asserting product-liability claims based on injuries she sustained from a medical device designed and manufactured by Bard. The jury found Bard liable for negligent failure to warn, awarding $1.6 million in compensatory damages and $2 million in punitive damages. On appeal, Bard argues that the district court erred by denying summary judgment on its preemption defense, that a failure-to-warn claim is unavailable in these circumstances, and that the award of punitive damages was not supported by the evidence. We affirm.

I

For more than a century, the Food and Drug Administration has been responsible for approving new

drugs before they enter the market. *See* 21 U.S.C. § 301 *et seq.* Until 1976, however, medical devices were not subject to FDA regulation. In the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, Congress provided for FDA regulation of medical devices.

The MDA directs the FDA to divide medical devices into three classes based on the level of risk they present, and it provides for different regulation of each class. 21 U.S.C. § 360c(a)(1). Class I, the lowest-risk category, comprises products such as bandages and tongue depressors. Class I devices are subject to "general controls" such as labeling requirements. *Id.* § 360c(a)(1)(A). Class II devices are those for which general controls "are insufficient to provide reasonable assurance of . . . safety and effectiveness." *Id.* § 360c(a)(1)(B). In addition to being subject to general controls, Class II devices are subject to "special controls" such as "performance standards, postmarket surveillance, . . . recommendations, and other appropriate actions as the [FDA] deems necessary" to ensure safety and effectiveness. *Id.* Class III devices, the highest-risk category, are devices that cannot be determined to provide a "reasonable assurance of . . . safety and effectiveness" under Class I or II controls, and that either are marketed as life-supporting devices or pose an unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

Class III devices are generally subject to premarket approval by the FDA. 21 U.S.C. § 360e. Premarket approval is a rigorous process that requires the manufacturer to submit a detailed application including studies of the device's safety and effectiveness. *See id.* § 360e(c)(1); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008). The FDA may approve the device only if has "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2)(A)–(B).

By contrast, Class I and II devices are generally subject to a far less rigorous process referred to as section "510(k) approval," *Riegel*, 552 U.S. at 322, which requires the manufacturer to show only that the device is "substantially equivalent" to an existing Class I or Class II device. 21 U.S.C. § 360c(f)(1)(A)(ii); *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996). To grant approval, the FDA must find that the device "has the same technological characteristics as the predicate device," or, if the device has different technological characteristics, that it "is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device." 21 U.S.C. § 360c(i)(1)(A).

This case involves an "intravascular filter," a device used in patients who have, or are at risk of developing, blood clots in the veins in their legs. Such clots can migrate to arteries in the lungs, causing a pulmonary embolism, a potentially life-threatening condition. Physicians can prescribe medications to inhibit clotting and prevent the formation of blood clots. But not all patients are able to use such medications. For those patients, physicians may prescribe an intravascular filter, which is implanted in the inferior vena cava, a large vein through which blood returns to the heart from the lower body. There, the filter can intercept clots before they travel to the lungs. (To visualize the filter, imagine the frame of an umbrella turned inside out by the wind. The spokes of the umbrella have small hooks that hold the structure in place on the walls of the vein.)

Until 2000, intravascular filters were regulated as Class III devices. In that year, the FDA issued a final rule reclassifying them as Class II devices and adopting three "special controls." 21 C.F.R. § 870.3375(b); *see* Medical Devices; Reclassification of 28 Preamendments Class III

Devices into Class II, 65 Fed. Reg. 17,138, 17,144 (Mar. 31, 2000). The first special control is the "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'" 21 C.F.R. § 870.3375(b)(1), which relates to biocompatibility and seeks to reduce "potential adverse tissue reactions" associated with "devices that contact the body." Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II, 64 Fed. Reg. 12,774, 12,777 (Mar. 15, 1999). The second special control is the "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)," 21 C.F.R. § 870.3375(b)(2)(i), which relates to sterilization and sets out "information about the use and application of national and international sterility consensus standards for devices to be labeled as 'sterile'" so as to reduce "[t]he potential risk of infection." 64 Fed. Reg. at 12,777. The third special control is the "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions," 21 C.F.R. § 870.3375(b)(2)(ii), which sets forth certain "labeling, biocompatibility testing, mechanical testing, sterilization procedures and labeling, and clinical data controls" related to intravascular filters, 64 Fed. Reg. at 12,778.

Bard manufactures several different intravascular filters, including the G2 Filter, which received section 510(k) approval in 2005. Bard distributed the G2 Filter with a label addressing various potential complications, including "fracture" (the filter breaks into pieces), "migration" (the filter moves from where the physician implanted it), and "perforation" (the filter, or fragments of the filter, punctures the wall of the vein). After it began selling the G2 Filter, Bard received reports of complications associated with the filter and conducted various internal analyses to review those risks. Its analysis revealed that the G2 Filter's rates of

fracture, migration, and perforation were significantly higher than those of other competing filters. Bard did not include that information in the product's labeling.

In 2007, Booker's physician implanted a G2 filter in her inferior vena cava. Several years later, after Booker began to experience severe pain, an examination revealed that the filter had fractured and perforated her inferior vena cava. She underwent two surgeries to attempt to remove the filter and its fractured pieces, but the surgeries were only partially successful, and one piece of the filter remains embedded in the wall of her inferior vena cava.

Booker brought this action against Bard in the District of Arizona as part of a multidistrict litigation involving thousands of similar cases. Booker is a resident of Georgia, and she asserted design-defect and failure-to-warn claims under Georgia law, which the parties agree governs this case.

Bard filed an omnibus motion for summary judgment for all cases in the multidistrict litigation, arguing that the MDA preempted all state-law claims. Bard relied in part on the MDA's express preemption clause, which preempts any state "requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). The district court denied the motion, reasoning that the MDA preempts state law only when the FDA has established "device-specific requirements," and concluding that the agency had not done so here.

After Booker's case was selected for trial, Bard filed a motion for partial summary judgment on all of Booker's claims, apart from the design-defect claims. As relevant

here, Bard argued that Booker's failure-to-warn claims were contrary to Georgia law. According to Bard, Georgia imposes on manufacturers a duty to warn of the risks posed by their products but does not impose a duty to warn about how those risks compare to the risks posed by other competing products. The district court denied summary judgment, concluding that the adequacy of the warning was a question for the jury.

At trial, the jury found Bard liable for negligent failure to warn, awarding $1.6 million in compensatory damages and $2 million in punitive damages. The jury found for Bard on the other claims. After trial, Bard challenged the sufficiency of the evidence to support the punitive damages award, but the district court held that the evidence, construed in favor of the verdict, "supported a finding that despite knowing that G2 filters placed patients at a greater risk of harm, Bard chose not to warn physicians and instead downplayed the risk."

Bard appeals.

II

We first consider whether Bard's preemption argument is properly before us. Bard raised its preemption defense only in its motion for summary judgment; it did not reassert the defense in a motion for judgment as a matter of law after trial. "Ordinarily, orders denying summary judgment do not qualify as 'final decisions' subject to appeal." *Ortiz v. Jordan*, 562 U.S. 180, 188 (2011) (quoting 28 U.S.C. § 1291). Relying on that principle, the Supreme Court held in *Ortiz* that an order denying summary judgment is generally not reviewable after trial. *Id.* at 184–85.

Before *Ortiz* was decided, however, we held that the general rule does not apply to purely legal issues—in other words, "to those denials of summary judgment motions where the district court made an error of law that, if not made, would have required the district court to grant the motion." *Banuelos v. Constr. Laborers' Tr. Funds for S. Cal.*, 382 F.3d 897, 902 (9th Cir. 2004). Purely legal issues, we held, *are* reviewable after trial even if raised only in a motion for summary judgment. *Id.* 902–03. Under *Miller v. Gammie*, 335 F.3d 889 (9th Cir. 2003) (en banc), we must continue to follow our decision in *Banuelos* unless it is "clearly irreconcilable" with later Supreme Court authority. *Id.* at 900.

We conclude that it is not. In *Ortiz*, the Supreme Court acknowledged the possibility that the general rule of non-reviewability might include an exception for "purely legal" issues, and the Court expressly declined to consider that question. 562 U.S. at 190. Because *Ortiz* allowed for the possibility of a *Banuelos*-like exception, it is not clearly irreconcilable with *Banuelos*. Indeed, several circuits have continued to recognize an exception for purely legal issues even after *Ortiz*. *See Frank C. Pollara Grp., LLC v. Ocean View Inv. Holding, LLC*, 784 F.3d 177, 185–86 (3d Cir. 2015) (citing cases).

Because the preemption issue here presents a purely legal question, we proceed to consider the merits of the district court's denial of summary judgment. Our review is de novo. *Banuelos*, 382 F.3d at 902.

The Supremacy Clause provides that the "Constitution, and the Laws of the United States" are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. The Supreme Court "has sometimes used different

labels to describe the different ways in which federal statutes may displace state laws," including "express, field, and conflict preemption." *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (plurality opinion). In this appeal, Bard invokes only the doctrine of express preemption, under which "Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision." *Arizona v. United States*, 567 U.S. 387, 399 (2012).

"When a federal law contains an express preemption clause, we 'focus on the plain wording of the clause.'" *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). As noted above, the MDA's preemption clause prohibits States from establishing any requirement with respect to a medical device "which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). Our interpretation of that provision is "'substantially informed' by the FDA regulation set forth" at 21 C.F.R. § 808.1(d), which addresses the statute's preemptive scope. *Riegel*, 552 U.S. at 322 (quoting *Lohr*, 518 U.S. at 495). That regulation provides that state requirements are preempted only when the FDA has established "specific requirements applicable to a particular device under the [MDA], thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements." 21 C.F.R. § 808.1(d).

Two Supreme Court cases guide our interpretation of the MDA and the regulation. First, in *Lohr*, the Court considered

product-liability claims asserted against the manufacturer of a device that had received section 510(k) approval. 518 U.S. at 480. The Court held that federal manufacturing and labeling requirements applicable to almost all medical devices did not have preemptive effect because they were not requirements specific to the device in question but instead reflected "entirely generic concerns about device regulation generally." *Id.* at 501. And although the FDA's determination of substantial equivalence under section 510(k) is device-specific, the Court rejected the proposition that section 510(k) approval itself imposed a "specific, federally enforceable design requirement" that preempts state law. *Id.* at 492. As the Court explained, when the FDA conducts substantial-equivalence review, it does not require a device "to take any particular form for any particular reason." *Id.* at 493.

In *Riegel*, by contrast, the Court held that the FDA's premarket approval of a medical device does establish device-specific federal requirements that can preempt state-law claims. 552 U.S. at 323. The Court emphasized that "premarket approval is specific to individual devices." *Id.* Unlike section 510(k) approval, the Court explained, premarket approval may be granted only if the FDA "determines that a device offers a reasonable assurance of safety and effectiveness." *Id.* Having made that determination, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id.*

For our purposes, the key principle established in *Lohr*—and confirmed in *Riegel*—is that "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device." *Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) (quoting

Anguiano v. E.I. Du Pont De Nemours & Co., 44 F.3d 806, 809 (9th Cir. 1995)); *accord* 21 C.F.R. § 808.1(d). *Lohr* further established that section 510(k) approval does not itself impose such device-specific requirements. 518 U.S. at 493–94.

Bard does not dispute either of those propositions. Instead, it argues that when the FDA reclassified intravascular filters as Class II devices, the agency imposed specific requirements in the form of the three special controls applicable to such devices. The preemption issue in this case therefore turns on whether the special controls constitute "specific requirements applicable to a particular device." 21 C.F.R. § 808.1(d).

As an initial matter, Booker argues that the special controls are not "requirements" because they are guidance documents that lack the force of law. Bard responds that the FDA has treated the special controls as if they were legally binding, not merely advisory. We need not resolve that dispute. Instead, we assume, without deciding, that the special controls are requirements, but we nevertheless conclude that they are not "specific" requirements "applicable to a particular device" under 21 C.F.R. § 808.1(d).

The lack of specificity of the special controls is particularly apparent in the case of the biocompatibility and sterilization guidance documents. The biocompatibility guidance addresses "risks to health related to adverse tissue reaction," which are "common to devices that contact the body." 64 Fed. Reg. at 12,777. The sterilization guidance addresses "risks to health related to infection," which are likewise "common to the use of many devices." *Id.* The former applies to 13 different kinds of devices, the latter to 18 kinds. *See* 65 Fed. Reg. at 17,140. Neither contains

anything specific to intravascular filters, let alone to the particular intravascular filter at issue here. Like the general requirements in *Lohr*, the documents "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." 518 U.S. at 501.

The intravascular-filter guidance is at least focused on the kind of device at issue here—intravascular filters. 64 Fed. Reg. at 12,778. Even so, we conclude that it does not have preemptive effect for two reasons. First, the guidance does not impose "specific requirements applicable to a *particular* device," 21 C.F.R. § 808.1(d) (emphasis added), such as Bard's G2 Filter. Instead, it applies generally to every member of the class of intravascular filters.

Second, the requirements that the intravascular-filter guidance imposes are not relevant to Booker's failure-to-warn claim. State requirements cannot meaningfully be described as "different from, or in addition to, the specific [FDA] requirements" if the two requirements are not relevant to each other. 21 C.F.R. § 808.1(d). Consistent with that understanding, the Supreme Court explained in *Lohr* that "in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a *relevant* federal 'requirement.'" 518 U.S. at 496 (emphasis added); *see id.* at 501 (explaining that preemption is appropriate when the FDA has "weighed the competing interests relevant to the particular requirement in question . . . and implemented that conclusion via a specific mandate on manufacturers or producers"). As Justice Breyer observed, it would make little sense to conclude that "the existence of one single federal rule, say, about a 2-inch hearing aid wire, would pre-empt

every state law hearing aid rule, even a set of rules related only to the packaging or shipping of hearing aids." *Id.* at 505 (Breyer, J., concurring in part and concurring in the judgment). In such a regime, the FDA would be forced to federalize all requirements for a particular device if it chose to adopt any requirement, because adopting just one requirement would displace all state regulation of that device.

Booker's claim is predicated on the theory that the G2 Filter's labeling was inadequate because it did not warn that the G2 Filter posed greater risks of migration and perforation than other kinds of filters. The intravascular-filter guidance does not prescribe the content of a filter's label in any manner relevant to such a warning. To be sure, the guidance says that the label should describe the product's indications for use ("for the prevention of recurrent pulmonary embolism via placement in the vena cava") and that it should state whether the device is safe in patients who may undergo an MRI. It also sets out one contraindication that the label should contain: "Vena Cava filters should not be implanted in patients with risk of septic embolism." But it says nothing about whether or how to warn of the risks of filter migration and perforation, and its only reference to the design of a particular device does not impose any requirement at all: "Your labeling may include other contraindications which are specific to your particular device design." As permitted by the guidance, the G2 Filter's label consists of two pages of detailed instructions, including 3 contraindications, 10 warnings, 11 precautions, and 15 potential complications, only one of which—the contraindication for patients at risk of septic embolism—has anything to do with the contents of the guidance.

We emphasize that the problem with Bard's preemption argument is not simply that the FDA did not prohibit Bard from adding additional warnings. The MDA's express preemption clause applies even when there is not a direct conflict between state and federal requirements, and it prohibits States from imposing a requirement "in addition to . . . any requirement" imposed by the FDA. 21 U.S.C. § 360k(a); *see McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted."); *accord Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (en banc) (Watford, J., concurring). Instead, the preemption argument fails because Booker's claim rests on an asserted state-law duty to warn of the risks posed by the particular design of Bard's G2 Filter, and the FDA has not imposed any requirements related to the design of that device or how a device of that design should be labeled. *Cf. Papike*, 107 F.3d at 741 (failure-to-warn claims were preempted "because the FDA ha[d] established specific counterpart regulations with respect to labeling" the product); *see also Lohr*, 518 U.S. at 496, 501.

III

Bard next argues that the district court erred in denying summary judgment on Booker's negligent failure-to-warn claim because Georgia law does not recognize a duty to warn of the comparative risks posed by different products.

Bard relies on *Farmer v. Brannan Auto Parts, Inc.*, 498 S.E.2d 583 (Ga. Ct. App. 1998), in which the court held that the distributor of a product "had no duty to communicate to users a danger already clearly listed on the product itself" by the manufacturer. *Id.* at 585. But as Bard acknowledges, *Farmer* did not consider comparisons of risks between

different products, so it has little relevance to the existence of a duty to provide such a comparison. Instead, Bard's theory is principally supported by non-Georgia decisions. For example, the Sixth Circuit, applying Ohio law, has held that a drug manufacturer must "make a reasonable disclosure of all the risks inherent in its own drug" but need not "provide a comparison of its drug with others." *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990); *accord Pluto v. Searle Labs.*, 690 N.E.2d 619, 621 (Ill. App. Ct. 1997).

There is some logic to those decisions: manufacturers generally do not have special access to information about their competitors' products, and such information might be difficult for consumers to evaluate meaningfully. On the other hand, a jury could find it significant that the warnings in this context are not provided directly to the ultimate consumer. Under the learned-intermediary doctrine, "the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). Comparative-risk information that might be meaningless to a layperson could be very important to a physician, or so a jury could find.

In any event, because this case is governed by Georgia law, our task is not to apply the rule we think would be best, or the rule we think is reflected in the leading decisions from state courts around the country. Rather, we must determine what rule the Georgia courts would apply. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78–80 (1938); *Norcia v. Samsung Telecomms. Am., LLC*, 845 F.3d 1279, 1284 (9th Cir. 2017).

The Georgia Supreme Court has held that "the manufacturer of a product which, to its actual or constructive knowledge, involves danger to users, has a duty to give warning of such danger." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994) (quoting *Ford Motor Co. v. Stubblefield*, 319 S.E.2d 470, 476 (Ga. Ct. App. 1984)). "Normally, where a warning has been provided by a manufacturer, '[t]he sufficiency of that warning is for the jury.'" *Copeland v. Ashland Oil, Inc.*, 373 S.E.2d 629, 630 (Ga. Ct. App. 1988) (quoting *Beam v. Omark Indus.*, 237 S.E.2d 607, 610 (Ga. Ct. App. 1977)). Georgia has not adopted a categorical prohibition on basing a failure-to-warn claim on the absence of a comparative warning. And other federal courts applying Georgia law have allowed such claims. *See, e.g.*, *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1220 (11th Cir. 1999); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1377–78 (M.D. Ga. 2010). Consistent with those decisions, we conclude that the district court correctly allowed the jury to decide the adequacy of the warning here.

IV

Finally, Bard argues that the district court erred by denying its renewed motion for judgment as a matter of law, which challenged the evidentiary sufficiency for the punitive damages award. We review the denial of such a motion de novo, viewing the evidence in the light most favorable to the verdict. *Harper v. City of Los Angeles*, 533 F.3d 1010, 1021 (9th Cir. 2008). We must uphold the punitive damages award "if it is supported by substantial evidence, which is evidence adequate to support the jury's conclusion, even if it is also possible to draw a contrary conclusion." *Id*. (quoting *Pavao v. Pagay*, 307 F.3d 915, 918 (9th Cir. 2002)).

Under Georgia law, a jury may award punitive damages when "it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b); *see Roseberry v. Brooks*, 461 S.E.2d 262, 268 (Ga. Ct. App. 1995) (explaining that an award of punitive damages requires "circumstances of aggravation or outrage"). The Georgia Supreme Court has articulated "a general rule" that punitive damages are "improper where a defendant has adhered to . . . safety regulations." *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993). But that rule does not "preclude[] an award of punitive damages where, notwithstanding the compliance with applicable safety regulations, there is other evidence showing culpable behavior." *General Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994), *abrogated on other grounds by Webster v. Boyett*, 496 S.E.2d 459 (Ga. 1998). When a failure to warn reflects "a conscious disregard for the safety of others," punitive damages may be appropriate. *Zeigler v. CloWhite Co.*, 507 S.E.2d 182, 185 (Ga. Ct. App. 1998).

Bard's challenge to the punitive damages award is largely derivative of its argument that it had no duty to warn of comparative risks. In Bard's view, punitive damages are inappropriate because it sold a product that was "not defective and sold with an adequate warning." But the jury found that the warning was not adequate. As the district court explained, "[t]he evidence supported a finding that despite knowing that G2 filters placed patients at a greater risk of harm" than other available filters, "Bard chose not to warn physicians and instead downplayed the risk." Although it would have been possible for the jury "to draw a contrary conclusion," we conclude that the evidence was adequate to

support the jury's award of punitive damages. *Harper*, 533 F.3d at 1021.

AFFIRMED.